K051076

ZOLL Medical Corporation

Worldwide Headquarters
269 Mill Road
Chelmsford, Massachusetts 01824-4105
U.S.A.

978 421-9655
978 421-0025 Main Fax

ZOLL

MAY 13 2005

510(k) Summary:

Submitter's Name and Address:

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Sean Reynolds
(978) 421-9386

Date Summary Prepared:

April 25, 2005

Device:

ZOLL ***stat***•pad***z***™ MwP Multi-function Electrodes

Classification:

Electrode, Electrodcardiograph, Multi-Function; Class II (21 CFR 870.2360)

Substantial Equivalence:

The features and functions of the ZOLL ***stat***•pad***z***™ MwP Multi-function Electrodes are substantially equivalent to those of the ZOLL ***stat***•pad***z***™ Adult Multi-function Electrodes K981802, cleared 11/25/1998, the Bio-Detek Tracerite ME40 SG ECG electrodes K964213, cleared 10/22/1996 and the Cardiotronics Systems, Inc. MODEL #918 Multi-Pads K883375, cleared 08/30/1988.

Description:

The disposable ZOLL ***stat***•pad***z***™ MwP Multi-function Electrodes are designed to provide both patient ECG monitoring and therapeutic capabilities in a single set of multi-function electrode pads. The ZOLL ***stat***•pad***z***™ MwP Electrodes will connect to ZOLL Medical Corporation defibrillator products for use on adult patients. The electrode pads include two therapy electrodes with permanently attached lead wires that join together in a proprietary ZOLL connector. Commonly used ECG monitoring electrodes are embedded within the anterior electrode backing but are electrically isolated from the therapy region. This configuration is designed to eliminate the need for, and time delay associated with, attaching up to 3 separate ECG electrodes.

Intended Use

The ZOLL ***stat***•padz™ MwP Multi-function Electrodes are intended for use by personnel who are trained in basic life support, or advanced life support, or other physician-authorized emergency medical response for external defibrillation, cardioversion, noninvasive pacing, and electrocardiograph monitoring. They are intended for use with all ZOLL Medical Corporation Defibrillator/Monitor/Pacemaker products.

Comparison of Technological Characteristics

The ZOLL ***Stat***•padz™ MwP Multi-function Electrodes maintain the same performance characteristics, features and functions to those of the ZOLL ***Stat***•padz™ Adult Multi-function Electrodes (K981802), and the Bio-Detek Tracerite ECG monitoring electrodes (K964213) and are provided in a configuration that is very similar to that of the Cardiotronics, Inc. MODEL #918 Multi-Pads (K883375).

Testing

The ZOLL ***Stat***•padz™ MwP Multi-function Electrode has been subjected to extensive performance testing to ensure that the device meets all of its functional requirements and performance specifications. Safety testing was performed to assure the device complies with applicable sections of recognized industry and safety standards.

Conclusion

Based on the results of the testing, the ZOLL ***Stat***•padz™ MwP Multi-function Electrodes has demonstrated that its features and functions are substantially equivalent to that of the indicated commercially distributed predicate devices with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2005

ZOLL Medical Corporation
c/o Mr. Sean Reynolds
Regulatory Affairs Engineer
Worldwide Headquarters
269 Mill Road
Chelmsford, Massachusetts 01824-4105

Re: K051076
Trade Name: ZOLL *stat*•padz™ MwP Multi-Function Electrodes
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrodes
Regulatory Class: II (two)
Product Code: MLN
Dated: April 22, 2005
Received: April 27, 2005

Dear Mr. Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K051076

Device Name: **ZOLL** ***Stat***•padz™ MwP Multi-function Electrodes

Indications for Use

ZOLL ***Stat***•padz™ MwP Multi-function Electrodes are indicated for the following clinical applications:

- Defibrillation
- Cardioversion
- Noninvasive Pacing
- Electrocardiograph Monitoring

These disposable electrodes will be used with the following devices:

- ZOLL PD™ 1200 Pacemaker/Defibrillator
- ZOLL PD™ 1400 Pacemaker/Defibrillator
- ZOLL PD™ 2000 Pacemaker/Defibrillator
- ZOLL D 900 Defibrillator
- ZOLL PD 1400 Defibrillator
- ZOLL D 2000 Defibrillator
- ZOLL 1600 Pacemaker/Defibrillator
- ZOLL 1700 Pacemaker/Defibrillator
- ZOLL M Series Equipment
- Future ZOLL Devices, as defined by ZOLL Operators Manuals

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051076